**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k051376

**B. Purpose for Submission:**

The purpose of this premarket notification is to provide results of a usability study performed to assess the ability of users to effectively run and distinguish between glucose and cholesterol tests offered on the AccuChek Instant Plus Dual Testing System, which is already being marketed. These tests were previously cleared individually under k944459 and k944458.

**C. Measurand:**

Glucose and Cholesterol

**D. Type of Test:**

Quantitative, electrochemical biosensor

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

AccuChek Instant Plus Dual Testing System

**G. Regulatory Information:**

1. Regulation section:

   21 CFR 862.1345 – Glucose test sytem

   21CFR 862.1175 – Cholesterol (total) test system

2. Classification:

   glucose - Class II

   cholesterol - Class I

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose

CHH, Enzymatic Esterase-Oxidase, Cholesterol

4. Panel:

Chemistry 75

**H. Intended Use:**

1. Intended use(s):
The Roche AccuChek Instant Plus Dual testing System is intended to be used for the quantitative measurement of glucose and cholesterol in capillary whole blood.

2. Indication(s) for use:
The Roche AccuChek Instant Plus Dual Testing System is designed to quantitatively measure cholesterol and glucose in capillary whole blood. The AccuChek Instant Glucose Test Strips are for use in home and professional settings for testing glucose in whole blood. The AccuChek Instant Plus Cholesterol Test Strips are for use by healthcare professionals and for home use by people with diabetes for cholesterol screening.

3. Special conditions for use statement(s): N/A

4. Special instrument requirements: N/A

**I. Device Description:**

The AccuChek Instant Plus Dual Testing System consists of a blood glucose/cholesterol meter, glucose test strips, and cholesterol test strips.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

AccuChek Instant Glucose Test System

AccuChek Instant Plus Cholesterol Test System

2. Predicate 510(k) number(s):

k944459

k944458

3. Comparison with predicate:

The meter and test strips have not been modified. They are exactly the same as those previously cleared individually.

**K. Standard/Guidance Document Referenced (if applicable):**

None

**L. Test Principle:**

The test systems use electrochemical biosensor technology. When blood is applied to the test strip, reagents on the strip react with the blood and a current is generated. The monitors employ amperometric technology to measure the glucose concentrations in the blood sample by measuring the amount of current that is generated when glucose reacts with the glucose oxidase on the glucose test strip and with esterase oxidase on the cholesterol test strip.. The result is the generation of current across the electrodes, which is proportional to the concentration of analyte present in the whole blood sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

The precision/reproducibility was cleared with the original 510(k)s for the Roche AccuChek Instant Glucose Test System (k944459) and the Roche AccuChek Instant Plus Cholesterol Test System (k944458).

*b. Linearity/assay reportable range:*

The linear range was cleared with the original 510(k)s for the Roche AccuChek Instant Glucose Test System (k944459) and the Roche AccuChek Instant Plus Cholesterol Test System (k944458).

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable.

*d. Detection limit:*

Detection limits of glucose is 20 – 600 mg/dL

Detection limits of cholesterol is 150-300 mg/dL

The detection limits were cleared with the original 510(k)s for the Roche AccuChek Instant Glucose Test System (k944459) and the Roche AccuChek Instant Plus Cholesterol Test System (k944458).

*e. Analytical specificity:*

The analytical specificity was cleared with the original 510(k)s for the Roche AccuChek Instant Glucose Test System (k944459) and the Roche AccuChek Instant Plus Cholesterol Test System (k944458).

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Clinical accuracy was demonstrated in the original 510(k)s for the Roche AccuChek Instant Glucose Test System (K944459) and the Roche AccuChek Instant Plus Cholesterol Test System (K944458).

*b. Matrix comparison:*

Not applicable.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

*c. Other clinical supportive data (when a. and b. are not applicable*):

Thirty subjects each performed two glucose and two cholesterol tests in alternating order using the AccuChek Instant Plus Dual Testing System. The study showed that users had no difficulty in differentiating between the two assays. Users identified and performed the tests correctly 100% of the time for N=30 users and N=120 tests. This met the study acceptance criteria of 90% or better within 95% confidence interval.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

Not applicable.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.